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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,466	01/03/2002	John D. Dobak III	051002	5793

7590

11/21/2003

INNERCOOL therapies, Inc.
3931 Sorrento Valley Blvd.
San Diego, CA 92121

EXAMINER

ROLLINS, ROSALIND STACIE

ART UNIT PAPER NUMBER

3739

DATE MAILED: 11/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,466

Applicant(s)

DOBAK ET AL.

Examiner

Rosiland S Kearney

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a device to treat tissue, classified in class 607, subclass 106.
- II. Claims 15-24, drawn to various methods, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case a materially different apparatus not including a dual balloon can practice the process.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention **of group I**: Species I in Figures 1a-b, Species II in Figures 2a-b.

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This application contains claims directed to the following patentably distinct species of the claimed invention **of group II**: Species I a method for reducing restenosis and Species II a method of reducing atrial fibrillation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Mark Weiczorek on 5/28/03 a provisional election was made without traverse to prosecute the invention of group I, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine '735. Lafontaine discloses a device to treat tissue comprising an outer tube (28), an inner tube (32) disposed at least partially within the outer tube and a dual balloon (14). Lafontaine teaches all of the structural components

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of the claims. The device of Lafontaine, however, has the structural components arranged differently such that the supply and return lumens are located on the exterior of the inner tube. Whereas the supply and return lumens of the present invention are located on the interior of the inner tube thereby causing the inlet to be defined solely by the outer tube and the inner tube. Therefore, without a showing of criticality it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the supply and return lumens of Lafontaine on the interior of the inner tube which would cause the inlet to be solely defined by the outer tube and the inner tube, since it has been held that rearranging parts of an invention involves only routine skill in the art.

Regarding claim 2 figure 2 illustrates the guidewire lumen, supply lumen and return lumen. **Regarding claim 6** (36) is illustrated as a marker. **Regarding claims 7-11** see col. 4 lines 49-52. **Regarding claims 13-14** see col. 4 line 26.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine further in view of Amplatz et al. '751. Lafontaine teaches all of the limitations of the claim except two radially extending tabs. Amplatz et al. disclose a balloon catheter that includes tab members to anchor the inner lumen of the catheter within the balloon while inflated. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include two tab members to anchor the inner lumen within the balloon while inflated. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to make the tabs integral with device, since it has been held that forming in one piece an article which

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has formerly been formed in two pieces and put together involves only routine skill in the art.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine further in view of Jacobsen et al. '101. Lafontaine teaches all of the limitations of the claim except a fluid contrast media. Jacobsen et al. teach that it is old and well known in the art to provide a contrast media as an inflation fluid for a balloon catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a fluid contrast media in the Lafontaine device as a means of inflating the balloon.

In the cross-sectional view of Figure 2 it does appear as if inner balloon (42) "rests on" tubes (30) & (44), as stated by Applicant. However, when put into the proper perspective of the actual 3-dimensional shape of the device, one would easily recognize that balloon (42) also "rests on" or is attached to tube (32) along those portions of the outer circumference not occupied by tubes (30) & (44).

Moreover, those portions of the circumference of tube (32) not occupied by tubes (30) & (44) form an inlet lumen with the inner circumference of tube (28).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S Kearney whose telephone number is 703/3082711. The examiner can normally be reached on Mon.-Fri. 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703/3080994. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703/3080758 for regular communications and 703/3080758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/3080858.

RK
May 30, 2003

A handwritten signature in cursive script that reads "Rosiland S. Kearney".

ROSILAND S. KEARNEY
PRIMARY EXAMINER